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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,696	10/09/2000	Tongtong Wang	210121.455C13	3927

7590 11/19/2003

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/685,696	WANG ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondenc address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-11,16,23-30,32-61,63,66 and 68* is/are pending in the application.

4a) Of the above claim(s) *4-11,16,23-30 and 32-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61,63,66 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-7-03 has been entered.

Claims 61, 63, 66 and 68 have been amended. Claims 62, 64, 65, 67, 69 and 70 have been canceled. Claims 4-11, 16, 23-30, 32-61, 63, 66 and 68 are pending and claims 61, 63, 66 and 68 are under consideration.

Priority

The priorities of Application Nos. 09/285,479, 09/221,107, 09/123,912, 09/040,802, and PCT US99/05798 are not granted because none of the applications disclose 100% amino acid sequence of SEQ ID No. 176. Thus, the effective priority date of SEQ ID No. 176 of the present application is the filing date of application No. 09/466,396, i.e. 12-17-99.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 61, 63, 66 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller-Pillasch et al., 1997 (Oncogene, Vol. 14, p. 2729-2733) in view of Carney (US Patent No. 6,200,764) and either Wong et al., 1999 (Journal of Immunology, Vol. 162, No. 4, p. 2251-2258) or Sjolancer et al., 1997 (Vaccine, Vol. 15, No. 9, p. 1030-1038).

Claims 61, 63, 66 and 68 are directed to a composition comprising an adjuvant and a polypeptide comprising SEQ ID No. 176, wherein said adjuvant induces a predominantly Th1-type immune response, the adjuvant includes OS21, SAF, ISCOMS etc.

Mueller-Pillasch teaches a human putative RNA binding protein KOC polypeptide sequence, SPTREMBL Accession No. O00425 (see computer printout mailed in preceding Official action), which is 100% identical to SEQ ID No. 176. Mueller-Pillasch also teaches that mRNA of the human KOC gene is highly overexpressed in pancreatic cancer cell lines and in pancreatic cancer tissue as compared to normal pancreas and chronic pancreatitis tissue (e.g. abstract).

Mueller-Pillasch does not teach combining the KOC polypeptide sequence with an adjuvant that induces a predominantly Th1-type response.

Carney teaches that Ras oncogene has been found in wide array of premalignant and malignant cells and activated or mutated Ras proteins has been found in primary and metastatic tumors. Carney teaches generation of recombinant normal or mutated Ras proteins by using

expression vector, production of polyclonal antibodies or monoclonal antibodies specific to Ras proteins, and detection, quantification of Ras proteins in body fluids, tissues, or cells by using said antibodies (e.g. abstract, column 1, 2, 8-10). Carney further teaches using carrier protein and complete Freunds adjuvant to enhance immunogenicity of the peptide (e.g. column 15).

Wong teaches adjuvant QS-21 or SAF-1 can stimulate predominantly Th1-type humoral immune response, which is reflected by the induction of IgG2a and IgG2b antibodies (e.g. abstract).

Sjolander teaches that immune stimulating complexes (ISCOMS) are 40 nm particles combining adjuvant-active Quillaja saponins and multimeric presentation of antigens, and ISCOMS efficiently recruit cells with Th1 properties (e.g. abstract).

It would have been obvious for one of ordinary skill in the art at the time of the invention to combine the human KOC polypeptide with adjuvant, such as QS-21 and SAF-1, to produce polyclonal antibody or monoclonal antibody specific to said KOC polypeptide because Mueller-Pillasch teaches that mRNA of the human KOC gene is highly overexpressed in pancreatic cancer cells as compared to normal cells and Carney teaches production of polyclonal antibodies or monoclonal antibodies specific to Ras proteins which is an oncoprotein, and teaches using carrier protein and complete Freunds adjuvant to enhance immunogenicity of the peptide. It would have been obvious for one of ordinary skill at the time of the invention to produce antibody that is specific to a tumor antigen, such as human KOC protein, for the detection of protein expression in tumor cells and normal cells. The teaching of Wong or Sjolander makes it obvious for one of ordinary skill in the art to use QS-21 or SAF-1, or ISCOMS adjuvant to induce predominantly Th1-type immune response.

One having ordinary skill at the time the invention was made would have been motivated to do so in order to produce antibody specific to the human KOC polypeptide more efficiently by using immunostimulant, such as adjuvant, as taught by Carney and use adjuvant, such as QS-21, SF-1 or ISCOMS, to induce predominantly Th1-type immune response as taught by Wong and Sjolander for detection and quantification of the human KOC protein in body fluids, tissues, or cells by using said antibody with reasonable expectation of success.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

Shin-Lin Chen